

In re Application of: Gad KEREN et al  
 Serial No.: 09/839,643  
 Filed: April 20, 2001  
 Office Action Mailing Date: March 24, 2008

Examiner: Nguyen, Camtu Tran  
 Group Art Unit: 3772  
 Attorney Docket: 34948

**In the Claims:**

1-48. (Cancelled)

49. (Previously presented) A method of decreasing blood pressure in a heart, comprising:

implanting a shunt with a valve element, between a left atrium and a right atrium of the heart.

50. (Previously presented) The method of claim 49 wherein said implanting includes deploying a tubular element having two ends and two fixation elements disposed at said two ends respectively.

51. (Previously presented) The method of claim 49, comprising allowing an amount of blood suitable to substantially reduce blood pressure in the left atrium, to flow from said left atrium to said right atrium via said shunt when the pressure differential between said left atrium and said right atrium reaches a threshold.

52-58. (Cancelled)

59. (Currently amended) A shunt for decreasing blood pressure in a heart, comprising:

a valve ~~suitable for operation implanting between chambers of a heart~~ a left atrium and a right atrium of the heart, ~~adapted to in which the valve opens only when~~ a pressure level between opposite ends of the valve is above a threshold pressure greater than a normal pressure level over the cardiac cycle between the left atria and the right atria of a normal heart.

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60. (Currently amended) A shunt according to claim 59, wherein the valve is ~~adapted to allow~~ passage of blood therethrough throughout the cardiac cycle.

61. (Currently amended) A shunt according to claim 59, wherein the valve is ~~adapted to be~~ shaped suitable for implanted-implantation in an internal wall of the heart.

62. (Withdrawn) A shunt according to claim 59, wherein the valve is purely mechanical.

63. (Currently amended) A shunt according to claim 59, wherein the valve is configured ~~adapted~~ to open under predetermined conditions which do not change without human intervention.

64. (Previously presented) A shunt according to claim 59, wherein the threshold has a value such that when a pressure difference between the left and right atriums is greater than the threshold, the patient is considered suffering from pulmonary edema.

65. (Previously presented) A shunt according to claim 59, wherein the threshold has a value such that when a pressure difference between the left and right atriums is greater than the threshold, the patient is considered in an exacerbated state of heart failure.

66. (Previously presented) A shunt according to claim 59, wherein the valve is configured to open only when a pressure between the opposite ends of the valve is between a lower pressure threshold and a higher pressure threshold.

67. (Currently amended) A shunt according to claim 59, comprising a shunt tube element encompassing the valve.

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68. (Currently amended) A shunt according to claim 67, wherein the shunt tube element has a diameter of less than 5 mm.

69. (Previously presented) A shunt according to claim 67, wherein the valve is configured to allow passage of a relatively small volume of blood relative to an ejection volume of the heart.

70. (Currently amended) A shunt according to claim 67, wherein the shunt tube element has a length not substantially greater than a thickness of walls between chambers of the heart.

71. (Previously presented) A shunt according to claim 59, wherein the valve allows continuous flow of a small amount of blood.

72. (Currently amended) A shunt according to claim 71, comprising a pump ~~adapted to~~ which induces the continuous flow of blood through the valve.

73. (Currently amended) A shunt according to claim 59, wherein the valve is ~~adapted to open~~ gradually.

74. (Previously presented) A shunt according to claim 59, wherein the valve is configured to close after the pressure level between opposite ends of the valve reduces by a predetermined value.

75. (Previously presented) A shunt according to claim 59, wherein the conditions which cause opening of the valve are adjustable from outside a patient's body when the shunt is implanted in the patient's heart.

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76. (Previously presented) A shunt according to claim 59, comprising at least one fixation element connected to the valve and adapted to be fixed to the heart.

77. (Previously presented) A shunt according to claim 76, wherein the at least one fixation element comprises at least two fixation elements.

78. (Previously presented) A shunt according to claim 77, wherein the valve is located in a tube and wherein a first one of the fixation elements is located on a first end of the tube and a second one of the fixation elements is located on a second end of the tube.

79. (Previously presented) A shunt according to claim 59, wherein the valve comprises a tubular element including at least a flat pivoting plate.

80. (Currently amended) A shunt according to claim 59, comprising a pump adapted to ~~for induce~~ inducing flow through the valve when the valve is open.

81. (Currently amended) A shunt according to claim 59, comprising an external indicator adapted to ~~for provide~~ providing an indication on a status of the valve.

82. (Currently amended) A shunt according to claim 81, wherein the external indicator is adapted to ~~indicates~~ indicates when the valve opens.

83. (Previously presented) A shunt according to claim 81, wherein the external indicator comprises a display.

84. (Currently amended) A method of controlled decreasing of blood pressure in a heart chamber, comprising:

providing a valve adapted to operate within a heart; and

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implanting the valve in a heart between two heart ~~chambers~~ atria, such that the valve opens responsive to a pressure level of an exacerbated state of heart failure but not under normal pressures of systole and diastole of a normal heart.

85. (Cancelled)

86. (Previously presented) The method of claim 84, wherein implanting the valve in the heart comprises implanting between a left atrium and a right atrium, such that opening the valve allows flow of blood from the left atrium to the right atrium.

87. (Previously presented) The method of claim 84, wherein providing the valve comprises providing a valve configured to open only when the pressure in the left atrium is above a predetermined threshold.

88. (Previously presented) The method of claim 87, wherein providing the valve comprises providing a valve configured to open only when the pressure in the left atrium is above 12mmHg.

89. (Previously presented) The method of claim 84, wherein implanting the valve comprises implanting in a manner which leads blood to the right ventricle.

90. (Previously presented) The method of claim 84, wherein implanting the valve comprises implanting in a septum.

91. (Previously presented) The method of claim 84, comprising notifying a physician when the valve opens.

92. (Currently amended) A method according to claim 84, wherein the valve is ~~adapted to allow~~ passage of blood therethrough only during diastole.

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93. (Currently amended) A method according to claim 84, wherein providing the valve comprises providing a valve including a signal processing element ~~adapted to~~ for controlling the opening of the valve.

94. (Previously presented) A method according to claim 93, wherein providing the valve comprises providing a valve including an intra-corporeal electrical battery configured to power the signal processing element.

95. (Previously presented) A method according to claim 93, wherein providing the valve comprises providing a valve including an externally coupled energy source which powers the signal processing element.

96. (Previously presented) A method according to claim 93, wherein the signal processing element is configured to adaptively change the conditions which cause opening of the valve.

97. (Currently amended) A method according to claim 84, wherein providing the valve comprises providing a valve including a sensor ~~adapted to~~ for sense sensing a state of the heart and wherein the valve ~~is adapted to~~ opens at least partially responsive to readings of the sensor.

98. (Previously presented) A method according to claim 84, wherein the valve is configured to open when the heart suffers from an exacerbated absolute arterial pressure or an exacerbated differential arterial pressure.

99. (Previously presented) A method according to claim 84, wherein the valve is configured to close after drainage of an amount of blood sufficient to reduce the mean left atrium pressure by 5mmHg.

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100. (Previously presented) A method according to claim 84, wherein the valve is configured to open responsive to a differential pressure level between its opposite ends.

101. (Previously presented) The method of claim 84, wherein implanting the valve comprises implanting in a percutaneous procedure.

102. (Previously presented) The method of claim 84, comprising puncturing a transseptal hole and wherein implanting the valve comprises implanting the valve in the transseptal hole.

103. (Currently amended) A shunt for installation in a heart, comprising:  
a valve suitable for operation ~~within~~ between atria of the heart;  
a sensor adapted to sense a parameter indicative of a state of the heart; and  
a controller adapted to open the valve at least partially responsive to readings from the sensor.

104. (Previously presented) A shunt according to claim 103, wherein the sensor comprises a pressure sensor.

105. (Currently amended) A shunt according to claim 104, wherein the controller is ~~adapted to open~~ the valve when the pressure read by the sensor is above a highest pressure in the left atrium in a normal heart.

106. (Previously presented) A shunt according to claim 105, wherein the valve is configured to open when the sensor indicates a pressure above 12mmHg.

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107. (Previously presented) A shunt according to claim 105, wherein the valve is configured to open when the sensor indicates a pressure above 15mmHg.

108. (Previously presented) A shunt according to claim 105, wherein the valve is configured to open when the sensor indicates a pressure above 20mmHg.

109. (Currently amended) A shunt according to claim 105, wherein the controller is ~~adapted to control~~ the opening of the valve at least partially responsive to a condition outside the heart.

110. (Previously presented) A shunt according to claim 103, wherein at least one parameter or rule governing the opening of the valve by the controller changes adaptively.

111. (Previously presented) The method of claim 49, comprising puncturing a transseptal hole and wherein implanting the shunt comprises implanting in the punctured transseptal hole.

112. (New) The method of claim 84, wherein implanting the valve in the heart comprises implanting between a first ventricle and a second ventricle.